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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,593

Applicant(s)

BOONE, CHARLES

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-10 and 73-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-10 and 73-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/25/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is a reply to the amendment and response of 18 November 2003 filed in reply to the Non-Final Office Action mailed 18 July 2003. Claims 11-72 were considered in the 18 July Office Action. Claims 2-5 and 11-72 were cancelled, claims 1, 6, and 7 were amended, and claims 73-82 were added in the 18 November Paper. Claims 1, 6-10 and 73-82 are pending and under consideration.

Response to Amendment

Rejection and objection to claims 2-5 is rendered moot by cancellation of the claims.

Specification

Objection to the specification is withdrawn in view of the amendments thereto.

Double Patenting

It was noted in the 18 July Office Action that copending applications 10/219,682 and 10/218,820 disclose subject matter in common with this application and may recite the same or overlapping inventions but were not available for review. The applications have been reviewed and the presently pending claims have been found to be distinct therefrom.

Claim Rejections - 35 USC § 112

Claims 1 and 6-10 stand rejected and newly added claims 73-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

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Claim Rejections - 35 USC § 102

Rejection of claims 1 and 7-9 under 35 U.S.C. 102(b) as being anticipated by Holzman *et al.* (1993) *J. Cell Biol.* 122:635-644 is withdrawn in view of the amendments to the claims.

Rejection of claims 1, 6, 7 and 10 under 35 U.S.C. 102(b) as being anticipated by Uetz *et al.* (2000) *Nature* 403:623-627 is withdrawn in view of the amendments to the claims.

Rejection of claims 1, 7 and 10 under 35 U.S.C. 102(b) as being anticipated by Ito *et al.* (2000) *Proc. Natl. Acad. Sci. USA* 97:1143-1147 is withdrawn in view of the amendments to the claims.

Rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Uetz *et al.* (2000) *Curr. Opin. Microbiol.* 3:303-308 is withdrawn in view of the amendments to the claims.

Response to Arguments

Claims 1, 6-10 and 73-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope for reasons set forth in the previous Office Action. The disclosure does not provide adequate written description for the broad class of all output arrays encompassed by the claims.

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In response to the rejection of record, Applicant has amended the claims to recite output arrays resulting from the mating of at least two input arrays, with at least one of the input arrays comprising starting yeast strains of deletion mutants from either *Saccharomyces cerevisiae* or *Schizosaccharomyces pombe* species and another of the input arrays comprising starting yeast strains carrying a genetic alteration linked to a dominant drug resistant marker.

Applicant argues that because the deletion mutants of *Saccharomyces cerevisiae* and *Schizosaccharomyces pombe* were known to skilled artisans at the time of filing the specification discloses relevant identifying characteristics to establish possession of the invention, in accordance with MPEP 2163(ii).

Applicant further asserts that the specification provides sufficient description of a representative number of species, since the application discloses that an output array of the present invention can result from the mating of 8 different strains of yeast carrying a genetic alteration linked to a dominant drug resistant marker with an array of close to 5,000 deletion strains from *Saccharomyces cerevisiae*.

These arguments have been fully considered but are not found persuasive. As pointed out in the previous Office Action, the claims encompass products having tremendously varied characteristics. The amended claims are directed to an array of yeast strains which are limited to comprising at least two mutations one of which must be a deletion. Although deletion mutants of *Saccharomyces cerevisiae* and *Schizosaccharomyces pombe* were known in the art, applicant is claiming to be in possession of all arrays comprising the deletion mutation and one or more genetic alterations in addition to the deletion. The additional genetic alterations comprised by the output arrays are essentially unlimited.

Although the new dependent claims provide some broad limitations on other genetic alterations comprised within the output array, these are set forth as broad classes which also lack adequate written description. For example, one embodiment limits at least one of the genetic alterations comprised within the array to an aptamer, wherein the aptamer can be a peptide aptamer or nucleic acid aptamer (i.e., claims 73 and 74). As the aptamer itself is an essential element of the claimed subject matter, the aptamer must be described. However, the specification teaches only that aptamers are peptide or nucleic acids that are produced through at least partially randomized pools for nucleic acid or amino acid sequences and selected for their ability to bind certain epitopes (paragraph [0043]). The skilled artisan would not recognize that Applicant was in possession of the full scope of any nucleic acid or amino acid sequence selected for its ability to bind certain epitopes because the disclosure provides nothing more than a broad recitation of function. Thus, claims directed to output arrays comprising said aptamers lack adequate description at least because the disclosure fails to adequately describe the aptamer itself. Similarly, the disclosure fails to adequately describe the claimed output arrays comprising all protein-protein interaction detection systems, and all heterologous genes at least because Applicant has not demonstrate possession of the protein-protein interaction detection systems and heterologous genes comprised by the output arrays.

With regard to the species reduced to practice, as pointed out in the previous Office Action, each of the 8 arrays differ only in the identity of a single yeast gene mutation. This clearly is not representative of the vast scope of the instant claims, which encompass output arrays comprising all genes encoding for aptamers, all protein-protein interaction detection systems, all heterologous genes either having or not having a yeast homologue and all mutations

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or deletions of endogenous yeast genes. Therefore, for reasons of record and herein above, only the output arrays actually reduced to practice in Example 6, which provide the data set forth in Table 1, meet the written description provision of 35 U.S.C. §112, first paragraph

New Grounds

Claim Objections

Claim 1 is objected to because of the following informalities: “*Cerevisiae*” is misspelled in line 10. Appropriate correction is required.

Claim 78 is objected to because it sets forth an abbreviation with no accompanying definition. Each abbreviation set forth in the claims should be defined the first time it is used.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is indefinite in the recitation of “heterologous gene” in line 4. Heterologous is a relative term; thus, interpretation of the limitation requires that the frame of reference be identified. In other words, it is unclear whether the heterologous gene must be the gene heterologous to yeast, to the particular species of yeast comprising the gene or to some other organism.

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Claim 78 is additionally indefinite in reciting, “the human gene comprises a set of alleles, each differing by one or more SNP’s”. Any given single gene comprised within a genetic construct such that it can be expressed in a heterologous system will by definition represent a single allele. It is therefore unclear what is meant in limiting the gene to comprising a set of alleles. Although it is possible that claim 78 is merely reciting properties of the gene as it occurs in nature it is unclear if this is what applicant intends because all human genes comprise a set of alleles differing by one or more SNP’s.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim construction

The instant claims are directed to output arrays made by a process of mating input arrays having certain characteristics. As a product-by-process, the claimed output array reads on an output array made by any means. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

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same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

Based on the limitations of the input strains set forth in claim 1, the broad claims are understood to read on any array of yeast strains having the following properties: multiple strains in the a haploid state; each strain contains at least two genetic alterations, one of which must be a deletion, wherein the genetic alterations are different in each yeast strain; the strains are selected from either *S. cerevisiae* or *S. pombe* species; and one genetic alteration must be linked to a dominant drug resistance marker.

With regard to claim 78, which limits the human gene to comprising a set of alleles each differing by one or more SNP's, it is understood that this is a statement of the general properties of the gene and, as these properties are characteristic of all human genes (*Id.*), the gene of the claims reads on any human gene.

Claims 1, 6, 7, 10, 73, 77-79 and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by Dawson *et al.* (filed 10 December 1999) US 6,232,074.

Dawson *et al.* teaches construction of a haploid output array wherein an input (or acceptor) array of *S. cerevisiae* or *S. pombe* strains comprising a deletion of an essential gene linked to a drug resistance marker (see, e.g., column 9, paragraph 2) is transfected with a library of plasmids carrying heterologous genes, the transformants are induced to sporulate and haploid yeast comprising both the deletion mutation and the heterologous gene are selected (i.e., a second genetic alteration; see especially the discussion beginning in the paragraph bridging columns 13 and 14 and continued through the first paragraph in column 15; also see Example 1).

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The output array of Dawson *et al.* would comprise multiple yeast strains in the a haploid state; each strain containing at least two genetic alterations, one of which is a deletion, wherein the genetic alterations are different in each yeast strain; the strains are selected from either *S. cerevisiae* or *S. pombe* species; and one genetic alteration is linked to a dominant drug resistance marker. Thus, absent evidence to the contrary, the output array of Dawson *et al.* is the same as the output array of the instant claim 1.

Furthermore, Dawson *et al.* teaches an output array comprising 10 to 100 or 100 to 1000 yeast strains located on plates according to claims 6 and 10 (see especially the first paragraph in column 24), and the output array of Dawson *et al.* comprises a second mutation of an endogenous yeast gene (i.e., the wildtype alleles of the recessive markers are inactivated; see especially column 11).

Finally, Dawson *et al.* teaches an output array comprising a human gene, which as discussed above would comprise a set of alleles differing by one or more SNP's according to claims 73, 77 and 78 (see especially Examples 3 and 4); Dawson *et al.* further teaches an output array comprising a selectable marker to permit efficient recovery of haploid spore progeny according to claim 79 (see especially the second full paragraph in column 12), and the drug resistance marker to which the deletion mutation of Dawson *et al.* is linked (*Id.*) anticipates the genetic tag of claim 81.

As Dawson *et al.* teaches an output array comprising all of the limitations of the instant claims 1, 6, 7, 10, 73, 77-79 and 81, the claims are anticipated by Dawson *et al.*

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

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